IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

WALTER SHUKER, et al.	:	CIVIL ACTION
	:	
v.	:	No. 13-6158
	:	
SMITH & NEPHEW PLC, et al.	:	

MEMORANDUM

Juan R. Sánchez, J. **August 13, 2015**

Plaintiffs Walter and Vivian Shuker ask this Court to certify for interlocutory appeal its March 31, 2015, Orders dismissing the Shukers' products liability-related claims against Defendants Smith & Nephew, Inc. (S&N) and Smith & Nephew plc (PLC). Plaintiffs also seek leave to take discovery regarding S&N's alleged off-label promotion of artificial hip components used in Walter Shuker's hip replacement surgery so they may attempt to replead a nonpreempted state-law claim based on such off-label promotion, consistent with the Court's dismissal order. For the reasons set forth below, both requests will be denied.

BACKGROUND

Plaintiffs filed their original Complaint in this action in state court in September 2013, seeking damages for injuries Walter Shuker sustained after undergoing hip replacement surgery with components manufactured by one or both Defendants and for Vivian Shuker's loss of consortium. The claims in the original Complaint—for negligence/negligence per se, strict products liability, breach of express warranty, breach of implied warranties, fraud, and loss of consortium—were based on the understanding that all of the artificial hip components used during Mr. Shuker's surgery—a femoral head, a femoral stem, an acetabular shell, and a metal liner for the shell—entered the market pursuant to what is known as the § 510(k) process, as opposed to the substantially more rigorous premarket approval (PMA) process. As explained in

the Court's March 31, 2015, Memorandum, the process by which a manufacturer receives authorization to market a medical device has significant implications with respect to the manufacturer's potential tort liability. In general, under the Medical Device Amendments of 1976 (MDA), state tort claims relating to the safety or effectiveness of a medical device that received premarket approval are expressly preempted, insofar as state tort law imposes on the manufacturer requirements that differ from or add to the federal requirements applicable to the device. Such claims are not preempted, however, as to devices cleared via the § 510(k) process.

S&N removed this case to federal court based on diversity jurisdiction in October 2013 and, after answering the Complaint, filed a motion for judgment on the pleadings. In its motion, S&N noted Plaintiffs "misapprehend[ed] the regulatory status of the . . . components used in [Walter Shuker's] surgery," S&N's Mem. in Supp. of Mot. for J. on the Pleadings 1, and argued their claims were expressly preempted because some of the components—including the metal liner—had received premarket approval.[1] Following a Rule 16 conference, held before Plaintiffs responded to the motion for judgment on the pleadings, the Court granted Plaintiffs' oral request for leave to amend their Complaint and denied S&N's motion without prejudice. At the same time, the Court entered a scheduling order setting a March 6, 2014, discovery deadline, which was later extended to May 5, 2014.

In December 2013, Plaintiffs filed their First Amended Complaint, again alleging that all of the components used during Mr. Shuker's surgery were part of Defendants' R3 Acetabular System, a § 510(k)-cleared device. Nevertheless, the First Amended Complaint included a new claim for negligence based on Defendants' alleged violation of certain FDA regulations in the event that such a "parallel" claim was necessary to avoid preemption. *See* First Am. Compl.

[1] S&N also argued the claims were inadequately pleaded.

¶ 84.[2] S&N promptly moved to dismiss the new Complaint, arguing most of Plaintiffs' claims were preempted because the R3 metal liner used in Mr. Shuker's surgery received premarket approval as part of a separate medical device, the Birmingham Hip Resurfacing (BHR) System, and Plaintiffs' nonpreempted parallel claim failed to comply with applicable pleading standards. After an oral argument, the Court denied the motion to dismiss in March 2014, finding the FDA documents S&N had attached to the motion fell short of establishing that the metal liner used in Mr. Shuker's surgery had, in fact, received premarket approval. Recognizing that the resolution of the preemption issue was potentially dispositive of most (if not all) of Plaintiffs' claims and it was therefore in the parties' interest for the Court to decide the issue at an early stage of the litigation, the Court exercised its discretion under Federal Rule of Civil Procedure 26(d) to amend the scheduling order so as to permit S&N an opportunity to revisit its preemption defense on a motion for summary judgment following a brief period of discovery. The Court deferred ruling on whether Plaintiff had adequately pleaded a parallel claim until the preemption issue was rebriefed.

The parties thereafter conducted discovery on preemption. As part of this discovery, Plaintiffs sought to depose Mr. Shuker's surgeon to determine whether S&N promoted the metal liner used in Mr. Shuker's surgery for off-label use with the R3 Acetabular System. S&N sought to preclude the deposition, and the Court granted the request, finding that whether S&N had engaged in off-label promotion was not relevant to whether Plaintiffs' claims were preempted because the First Amended Complaint—which was premised on the theory that the metal liner

[2] The MDA preempts state tort claims only when the duties state tort law imposes on a device manufacturer differ from or add to the federal requirements applicable to the device in question. The MDA does not preempt state tort claims that are premised on violations of the federal requirements as "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

was part of the § 510(k)-cleared R3 Acetabular System—did not include any claims based on off-label promotion.

Following completion of the preemption discovery, S&N filed a motion for summary judgment on the issue of preemption and sought dismissal of Plaintiffs' parallel claims as inadequately pleaded. Plaintiffs opposed the motion and also filed a motion for leave to amend their First Amended Complaint so as to (1) clarify the regulatory status of the components used in Mr. Shuker's surgery based on the results of the preemption discovery,[3] (2) add claims based on Defendants' alleged off-label promotion of the metal liner, and (3) clarify their parallel claims. In addition, PLC, S&N's English parent company (through a series of intermediaries), filed a motion to dismiss this action for lack of personal jurisdiction.

On March 31, 2015, this Court granted Plaintiffs' motion for leave to amend and, treating Plaintiffs' Second Amended Complaint as the operative complaint, granted S&N's motion for summary judgment/dismissal, concluding that most of Plaintiffs' claims were preempted and that any nonpreempted claims based on Defendants' alleged violations of federal law lacked the facial plausibility necessary to survive a motion to dismiss. The Court granted Plaintiffs leave to amend their parallel claims based on off-label promotion, a theory Plaintiffs had not previously pursued. In a separate Order, the Court granted PLC's motion to dismiss, finding Plaintiffs had failed to establish a prima facie case that PLC was subject to personal jurisdiction in Pennsylvania and denying Plaintiffs' request for jurisdictional discovery.

[3] Discovery confirmed both that the metal liner used in Mr. Shuker's surgery received premarket approval as part of the BHR System and that the FDA had never approved the metal liner for use with the other components of the R3 Acetabular System in a hip replacement.

DISCUSSION

A. Motion for Discovery

Plaintiffs now seek formal discovery on the issue of off-label promotion before filing a further amended complaint. Plaintiffs argue such discovery is necessary because they lack personal knowledge as to how S&N marketed the R3 metal liner to physicians such as Mr. Shuker's surgeon, the public information available to them on this issue is limited, and the surgeon has retained his own counsel and is not cooperating with Plaintiffs.

Although Plaintiffs invoke Federal Rule of Civil Procedure 26(b)(1)[4] in their motion for discovery, given the current procedural posture of this case, they are, in essence, seeking pre-complaint discovery in order to investigate whether S&N engaged in off-label promotion and whether such off-label promotion played a role in Mr. Shuker's surgeon's decision to use the R3 metal liner in Mr. Shuker's hip replacement surgery, despite the lack of FDA approval for such use. The Federal Rules of Civil Procedure do not authorize such pre-complaint discovery, except as needed to perpetuate testimony that might otherwise be lost. *See* Fed. R. Civ. P. 27(a)(3) (authorizing depositions to perpetuate testimony as necessary to "prevent a failure or delay of justice"); *see also Ash v. Cort*, 512 F.2d 909, 912 (3d Cir. 1975) (holding "Rule 27 is not a substitute for discovery" but "is available in special circumstances to preserve testimony which could otherwise be lost"); *Mixing & Mass Transfer Techs., LLC v. Lightnin, Inc.*, No. 05-1519, 2006 WL 140414, at *3 & n.3 (M.D. Pa. Jan. 18, 2006) (directing plaintiff to file an amended complaint with a more definite statement of its fraud claim and dismissing references in plaintiff's briefs to pre-complaint discovery as "no such pre-complaint discovery is available under the Federal Rules of Civil Procedure"); *In re Chester Cnty. Elec., Inc.*, 208 F.R.D. 545,

[4] Rule 26(b)(1) authorizes a court, "[f]or good cause," to "order discovery of any matter relevant to the subject matter involved in the action."

547 (E.D. Pa. 2002) (noting the Third Circuit "has decisively rejected the attempt to use Rule 27(a) as a mechanism to draft a complaint or conduct pre-trial discovery").[5] Plaintiffs have made no showing that, absent pre-complaint discovery, testimony or tangible evidence is likely to be lost in this case.

Plaintiffs also argue discovery is necessary in light of the level of detail the Court expects from their pleadings, which they contend may be unrealistic without discovery. Plaintiffs note that other courts have recognized the difficulty of pleading a parallel claim with respect to a PMA-approved device, given that information regarding the applicable federal requirements, such as the terms of the FDA's premarket approval, are confidential. *See* Pls.' Mem. in Supp. of Mot. for Discovery 7-8 (citing *Swisher v. Stryker Corp.*, No. 14-28, 2014 WL 1153716 (W.D. Okla. Mar. 14, 2014), and *Killen v. Stryker Spine*, No. 11-1508, 2012 WL 4482371 (W.D. Pa. Aug. 21, 2012), *report and recommendation adopted as modified by* 2012 WL 4498865 (W.D. Pa. Sept. 28, 2012)). Neither case cited by Plaintiffs supports their request for discovery as both address how federal pleading standards should be applied when information about the federal requirements with respect to a medical device is unavailable to the plaintiff, not the availability of pre-complaint discovery in such cases. Insofar as Plaintiffs disagree with this Court's application of the pleading standards to the parallel claims in their Second Amended Complaint, they may obtain immediate appellate review by electing to stand on that complaint.

[5] Plaintiffs cite *Reints v. Sheppard*, 90 F.R.D. 346 (M.D. Pa. 1981), in support of the proposition that pre-complaint discovery is proper "when the 'critical information lies within the exclusive possession of the defendants.'" Pls.' Mem. in Supp. of Mot. for Discovery 6 (quoting *Reints*, 90 F.R.D. at 347). In *Reints*, however, the court specifically acknowledged that discovery of information needed to frame an amended complaint "is not the type of discovery envisioned in Rule 27(a)." 90 F.R.D. at 347. And while the court indicated it "would be willing to grant" a request for such discovery "in a situation where plaintiff truly did not have knowledge of sufficient facts to plead his case," the court had no occasion to actually decide the issue, as the plaintiff was "not in that predicament." *Id.* at 347-48.

Because Plaintiffs have not shown pre-complaint discovery is warranted, their motion for leave to take such discovery will be denied.

B. Motion to Certify

Plaintiffs also ask this Court to certify for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) its Order dismissing most of their claims as preempted by the MDA as well as its Order dismissing PLC for lack of personal jurisdiction. A district court may make such certification when (1) the order at issue "involves a controlling question of law"; (2) the controlling question of law is one "as to which there is substantial ground for difference of opinion"; and (3) "an immediate appeal from the order may materially advance the termination of the litigation." 28 U.S.C. § 1292(b). The party seeking certification must show all three factors are met. *Duffy v. Lawyers Title Ins. Co.*, No. 11-4503, 2012 WL 2527027, at *2 n.6 (E.D. Pa. July 2, 2012). The certification procedure is to be "sparingly applied." *Milbert v. Bison Labs., Inc.*, 260 F.2d 431, 433 (3d Cir. 1958). As the Third Circuit has recognized, § 1292(b) "is to be used only in exceptional cases where an intermediate appeal may avoid protracted and expensive litigation and is not intended to open the floodgates to a vast number of appeals from interlocutory orders in ordinary litigation." *Id.*

The Court agrees with Plaintiffs that the Court's preemption ruling presents controlling questions of law, including whether the MDA preempts state tort claims concerning the safety or effectiveness of a non-FDA-approved medical device created by a physician's use of a component of a PMA-approved device off-label with components from a § 510(k)-cleared device. *See Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974) (holding a controlling question of law encompasses "every order which, if erroneous, would be reversible error on final appeal" as well as questions "serious to the conduct of the litigation, either

practically or legally"). In concluding Plaintiffs' claims are preempted, this Court recognized that there is scant case law addressing the MDA's preemption provision in these unusual circumstances. Given the lack of authority on point and the different conclusions reached by those few district courts that have addressed the same or similar issues,[6] the Court also agrees the preemption question in this case is one as to which there is substantial ground for difference of opinion. *See In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d 701, 706 (M.D. Pa. 2009) (holding "[t]he existence of conflicting judicial opinions provides support for certification of an appeal, as does a lack of binding precedent").

Plaintiffs have not shown, however, that allowing an immediate appeal would materially advance the termination of this litigation. This third requirement for certification is met if an appeal "could eliminate the need for a trial, simplify a case by foreclosing complex issues, or enable the parties to complete discovery more quickly or at less expense." *Id.* at 707. In this case, an immediate appeal, if successful, would expand the claims Plaintiffs may pursue, thereby expanding the scope of discovery and trial. *See L.R. v. Manheim Twp. Sch. Dist.*, 540 F. Supp. 2d 603, 613 (E.D. Pa. 2008) (denying certification when a successful interlocutory appeal "would result in neither the termination nor the narrowing of th[e] litigation"). Plaintiffs argue this third requirement for certification is satisfied because a successful appeal would render litigation of any surviving parallel claims unnecessary. *See* Pls.' Mot. for Certification ¶ 6. But this argument is entirely hypothetical at this juncture as Plaintiffs have yet to plead a plausible

[6] As discussed in the Court's March 31, 2015, Memorandum, the two district courts that have considered the preemption issue with respect to the device at issue in this case have concluded that claims relating to the R3 metal liner or to the liner's interface with other components are preempted. *See Simon v. Smith & Nephew, Inc.*, 18 F. Supp. 3d 423, 428-29 (S.D.N.Y 2014); *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 254-58 (E.D.N.Y. 2014). A district court presiding over multidistrict litigation regarding a different medical device in West Virginia has disagreed with this analysis. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 749-52 (S.D. W. Va. 2014).

state tort claim based on off-label promotion. If Plaintiffs are unable to state a plausible parallel claim, this case will soon be ripe for a final appeal of all issues. Further, it remains to be seen whether Plaintiffs would voluntarily relinquish any such claims in the event of a successful appeal. Because Plaintiffs have not shown an immediate appeal would materially advance the termination of this action, certification of the Court's preemption ruling is not warranted.

Plaintiffs address this Court's Order dismissing PLC for lack of personal jurisdiction only briefly. They suggest certification of that Order is warranted because another federal district court held a different plaintiff had made a prima facie showing that personal jurisdiction could be exercised over PLC in New York based on allegations that PLC placed the hip replacement system at issue in the stream of commerce in New York and recruited the plaintiff's New York surgeon to attend a training session in England so that the surgeon could market the hip replacement system to his New York patients. *See Gale v. Smith & Nephew PLC*, No. 12-3614, 2015 WL 328127, at *3-4 (S.D.N.Y. Jan. 20, 2015). Plaintiffs acknowledge that, unlike the plaintiff in *Gale*, they have not alleged that PLC specifically targeted Mr. Shuker's surgeon in the forum state, an allegation crucial to the court's decision in *Gale*. *See id.* at *3 (noting "PLC's expectation that the System would be shipped, purchased, and used in New York, alone, may be insufficient to show PLC transacted business in New York," but, "combined with [Defendants'] recruitment of [the plaintiff's surgeon], [wa]s sufficient to show PLC purposefully availed itself of New York's market"). They argue, however, that this Court committed reversible error by not permitting jurisdictional discovery.[7]

[7] Plaintiffs' suggestion that the Court ignored their request for jurisdictional discovery and the proposed discovery they sought to take is incorrect. Contrary to Plaintiffs' assertion, the Court denied their request for jurisdictional discovery, finding Plaintiffs had failed to "present[] factual allegations that suggest with reasonable particularity the possible existence of the requisite

Because the denial of a request for jurisdictional discovery may constitute reversible error, this Court assumes the denial of such discovery in this case is controlling question of law.[8] *See Katz*, 496 F.2d at 755. *But see In re Carco Elecs.*, 536 F.3d 211, 214 n.6 (3d Cir. 2008) (observing that discovery orders "will not ordinarily present a controlling question of law"). Nevertheless, Plaintiffs have made no showing that there is a substantial ground for difference of opinion as to whether such discovery was warranted in this case and offer no explanation as to how an immediate appeal from this Order would materially advance the ultimate termination of this litigation. Certification is therefore not warranted as to the Court's jurisdictional ruling.

For the reasons set forth above, Plaintiffs' motions for leave of court to take discovery and to certify orders for interlocutory appeal will be denied. An appropriate order follows.

BY THE COURT:

/s/ Juan R. Sánchez
Juan R. Sánchez, J.

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contacts between [PLC] and the forum state." Order 5, Mar. 31, 2015, ECF No. 90 (quoting *Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003)).

[8] Plaintiffs do not argue this Court erred in holding they had failed to establish a prima facie case of personal jurisdiction on the existing record, but instead maintain the Court erred in not permitting jurisdictional discovery.